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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,036	07/30/2001	Kiran Madura	266/165	1466
34055	7590	04/07/2006	EXAMINER	
PERKINS COIE LLP POST OFFICE BOX 1208 SEATTLE, WA 98111-1208			WALICKA, MALGORZATA A	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 09/918,036	Applicant(s) MADURA, KIRAN	
	Examiner Malgorzata A. Walicka	Art Unit 1652	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 February 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 6,7,9,10 and 12.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see the attached.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: PTO form 892.

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Reply under 37 CFR section 1.116 filed Feb. 27, 2006 is acknowledged. Claims 6 and 10 have been currently amended. Claims 6, 7, 9, 10 and 12 are pending.

ADVISORY ACTION

1. 35 USC, section 112, first paragraph

Lack of written description

Amended claims 6-7, 9, 10 and 12 are directed to the transformed yeast cells and a DNA construct to be used for assessing whether a yeast with catalytically active 26S proteasome is quiescent or actively growing.

The claims remain rejected because neither the specification nor the claims as originally filed define the term "catalytically active 26S proteasome". The disclosure does not provide a defining characteristic of the term "catalytically active 26 proteasome". Firstly, the term catalytic activity as related to proteasome 26S is generic, as the proteome comprises catalytic complexes- see Tanaka, page 537, the subtitle in the right column. Tanaka teaches also that proteolysis is not the only function of 26S complex. On page 538 he mentions the role of proteasome in production of MHC class I ligands. The term "catalytically active 26S proteasome" as used by Applicants is also generic because 26S proteasome is a very complex structure and there is no teaching in the specification which mutants of which components of the proteasome do not influence its catalytic activity and which do so. Applicants themselves describe on page 2 of the specification, line 30 and further, and on page 3, line 12 and further, the structure of 26S proteasome as an extremely complex structure. It consists of two

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subcomplexes, a catalytical one of 20S and a regulatory one of 19S. In line 20 on page 3 Applicants inform,

“The 19S complex contains as many as 20 subunits, which include a multiubiquitin-chain binding protein, isopeptidases and at least 6 ATPases. To date, many of these additional subunits remain uncharacterized.”

Thus, the state of the art at the time of filing did not allowed for unequivocal definition of the term “catalytically active 26S proteasome”. Thus, because of lack of description of the criteria for “catalytically active 26 proteasome”, one having skills in the art, would not know how to select a yeast cells suitable for performing the method. In conclusion, because the Applicants did not reasonably convey to one skilled in the relevant art that at the time the application was filed they had possession of the claimed invention, the claims are rejected.

Scope of enablement

Claim 6-7 and 9, 10 and 12 remain rejected for scope of enablement, although the claims are now limited to application of the method to yeast cells. The reasons for rejection are explained in the final rejection of Nov. 30, 2005.

Response to Applicants' arguments

In their Remarks, on page 6, Applicants write, “As is well-known in the art, defects in the ATP-dependent proteasome pathway generally result in lethality and only conditional mutants can be analyzed, as exemplified in the instant specification. “

This argument of Applicants is not persuasive, because the claims do not exclude any mutants caused by defective ATPases of proteasome 26S. Furthermore, not only defective ATPases can render the proteasome 26S inactive. Tanaka, on page 539, left column, third paragraph, emphasizes "The PA700 regulatory complex [19S subunit] has approximately 14 non-ATPase subunits that seem to play a pivotal role in the functions of 26S proteasome. However, the functions of many of these non-ATPase subunits are largely unknown." He continues in the first paragraph of the right column on the same page, "Of note, dysfunctions of certain no-ATPase subunit genes result in growth arrest at various stages of the cell cycle." These mutants, obviously known to those having skills in the art at the time of invention, have not been excluded from the claimed method as well. In conclusion, the scope of the claims is not sufficiently described and for that reasons the claims may not be given the broadest reasonable interpretation as Applicants emphasizes in REMARKS, page 6, third paragraph.

On page 7, Applicants emphasize that in the light of the teachings in the specification the term "catalytically active 26S proteasome" has a plain meaning, i.e., to degrade Ubl containing proteins, and because of that Applicants were in possession of that which is claimed.

This argument of Applicant is not persuasive, because, as explained in previous Office Actions, the specification does not provide an unequivocal correlation between Ubl protein degradation and active growth of transformants. The specification teaches only how to determine whether a cell degrades Ubl or not.

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2. Conclusion

All claims remain rejected.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.

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Patent Examiner


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